THIRTY-SIXTH MEETING

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

May 24, 2000

National Institutes of Health
Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened for its thirty-sixth meeting on May 24, 2000, in Conference Room 6, Building 31-C, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Open: May 24, 2000: 8:30 a.m. to 12:30 p.m., for the review and discussion of program development, needs and policy; and

Closed: May 24, 2000: 12:30 p.m. to 2:30 p.m. for review of individual grant applications.

Council members present:[1]

Dr. Rita S. Berndt
Dr. Gail D. Burd
Dr. Bernard Cohen
Dr. David P. Corey
Dr. Robert R. Davila
Ms. Rebecca S. Dresser
Dr. Judy R. Dubno
Ms. Jane H. Fraser
Dr. Ronald R. Hoy
Dr. Jacqueline E. Jones
Dr. Miriam H. Meisler
Dr. Everett R. Rhoades
Ms. Donna L. Sorkin
Dr. Bettie M. Steinberg
Ms. Virginia W. Stern
Dr. Gregory T. Wolf

Council member absent:
Dr. Bernard Harris
Dr. Orlando Taylor

1For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "en bloc" actions.

Ex-Officio Members present:

Dr. Lucille B. Beck

Ex-Officio Members absent:

Dr. John R. Franks
Dr. Michael E. Hoffer

The Council roster is found as Appendix 1.

Various members of the public, as well as NIDCD staff and other NIH staff, were in attendance during the open session of the Council meeting. A complete list of those present for all or part of the meeting is found in Appendix 2.

I. Call To Order and Opening Remarks ..... Dr. James F. Battey, Jr.

The meeting was called to order by Dr. Battey, Director, NIDCD, who expressed his appreciation to all Council members for their service and advice to the Institute.

II. Council Procedures ..... Dr. Craig A. Jordan

Procedural Matters

Dr. Jordan discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members avoiding conflict of interest, or the appearance thereof, was stressed, as was the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Jordan announced that the Council meeting would be open to the public during the morning session, but would be closed for consideration of grant applications during the afternoon.

Consideration of Minutes from the Meeting of January 21, 2000

Dr. Battey called members' attention to the Minutes of the Council's meeting of January 21, 2000. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2002 have been established. A list of these meetings was distributed to the Council members. The next meeting of Council is scheduled for Friday, September 15, 2000 and will be held off-campus in the Neurosciences Center, 6001 Executive Boulevard, Rockville, MD.

III. Report of the Director, NIDCD ..... Dr. Battey

Budget Considerations

Dr. Battey discussed the Institute's projected budget for FY 2001. Using a pie chart, he indicated that the Research Project Grants category will be $196 million or 70.5%,of the entire appropriation. Other budget categories include $14 million (5.0%) for R&D contracts; $24 million (8.6%) for Intramural Research; $10 million (3.6%) for Research Management and Support; $9 million (3.2%) for Research Training; $5 million (1.8%) for Other Research; and $20 million (7.2%) for Research Centers.

Dr. Battey next discussed how the nearly $51.5 million available for competing research project grants will be allocated for FY2000 initiatives. After consideration of pre-existing commitments, approximately $14.7 million is available for the May Council. As is traditionally done in the NIDCD, 15 percent of this ($2.2 million) will be designated for High Program Priority. This leaves approximately $12.5 million available for the initial payline, to the 30th percentile.

Copies of the slides Dr. Battey used for his budget presentation are included in these Minutes as Appendix 3.

First-Time Investigators

Next, Dr. Battey addressed the issues surrounding the shortage of first-time investigators, stressing the need to "get good, young people into the pipeline." Dr. Luecke commented on NIH's philosophy in classifying first-time investigators, and how the research community is being impacted. Dr. Battey discussed tentative plans to initiate an "augmented" review process that would allow first-time investigators to address concerns raised in summary statements more quickly than the standard amended application process. He asked for Council comments regarding the current shortage of first-time investigators and for suggestions about the plan for expedited review.

Council members perceive a variety of reasons for this problem. One member reported that space in laboratories is an important issue, adding that senior investigators are reluctant to share shrinking laboratory space with new investigators. Another member commented that there is not enough time for mentoring. The question was raised about how the demise of the R29 may have added to the problem because new investigators often mistakenly believe that they can't qualify for R01 paylines. NIH's policy for scoring new investigators was also questioned; right now, approximately one-half of new investigators are not scored and some Council members believe that new applicants might benefit from full discussion (and scoring) by the entire initial review group. New investigators often don't realize the benefit of contacting program administrators for assistance with their applications. A member stressed that a quicker review turnaround time is critical, adding that reviewers sometimes seem unaware of which applications are coming from new investigators.

Members were quite supportive of an NIDCD initiative to provide a more rapid means by which first-time investigators would address reviewer concerns. It was suggested that the Institute could publicize its interest in supporting first-time investigators by posting an announcement on the NIDCD Web Site.

Dr. Battey thanked the Council for their comments, and indicated that a plan for expedited review would be developed for first-time R01 applicants.

IV. Report of the Director, Division of Extramural Research ..... Dr. Robert Dobie

Solicitation of Initiatives

Dr. Dobie reported that in early May, a letter was distributed widely to the research community to solicit ideas for new research initiatives. NIDCD's first priority is the funding of high quality research conceived and initiated by members of the research community. This has been emphasized in the Institute's strategic plan which was structured to draw attention to extraordinary research opportunities and compelling needs; the NIDCD Strategic Plan has been posted on the NIDCD web site (http://www.nih.gov/nidcd/about/director/strategic.htm) During the next year, NIDCD staff will be developing a series of specific initiatives to address these opportunities and needs, as well as others that emerge from interactions with the research community. Dr. Dobie urged Council to help with this effort by encouraging their colleagues to share their ideas with Dr. Battey or him at any time.

Change in Clinical Trial Support

Dr. Dobie reported that NIDCD has adopted a modified approach to the funding of clinical trials. To implement this modification, two companion Program Announcements (Pas) have been published in the NIH Guide. One is entitled “NIDCD Clinical Trial Planning Grant” (PAR-00-007), and provides support for initial studies leading to the development of a Manual of Procedures and other related activities necessary before conducting a full clinical trial. The other is entitled “NIDCD Investigator-Initiated Clinical Trials” (PA-00-107) and indicates the requirements placed on the receipt, review, and funding of clinical trials applications.

Conference Grant Review

Dr. Dobie discussed the possibility of changing the review process of the conference grant. The Institute will consider conducting the second level of review of conference grants within the Institute and providing Council information about these actions as part of their Interim Actions report. This change could result in a 10-week reduction in the review process, from receipt to second level review.

Program Activities

Dr. Dobie highlighted a Request for Applications (RFA) and a Program Announcement for which applications are being sought. The RFA, for minority dissertation research grants in human communication, will offer small grants to support doctoral dissertation research in human communication by minority doctoral candidates. The goals of this program are to aid the research of new minority investigators and to encourage minority individuals from a variety of academic disciplines and programs to conduct research in hearing, balance, smell, taste, voice, speech, and language. Applications in response to this announcement are due by June 28, 2000.

The PA is for feasibility studies of high impact research focused on the scientific mission areas of the NIDCD. High impact research involves pilot/feasibility studies in which the technological, methodological, or theoretical approach to a problem lacks a historical precedent or sufficient preliminary/baseline data, but whose successful outcome would have a major impact on a scientific area or field. This research program will be supported through the Exploratory/Developmental (R21) Grant mechanism. These grants provide support for feasibility studies to generate preliminary data that would serve as a basis for more extensive research projects. Applications in response to this announcement are due by July 21, 2000.

Dr. Daniel Sklare is overseeing both of these initiatives.

Staff Recruitment

Dr. Dobie reported that Dr. Beth Ansel, of the Scientific Programs Branch, has accepted a position with the National Institute of Child Health and Human Development, NIH. The Branch is currently recruiting a replacement for Dr. Ansel's position, and Dr. Dobie encouraged Council's participation in this recruitment.

V. "Mammalian Taste Receptors" ..... Dr. Nicholas Ryba

Dr. Battey introduced Dr. Nicholas Ryba, of the Division of Intramural Research, National Institute of Dental and Craniofacial Research. Dr. Ryba discussed recent research findings in the area of mammalian taste receptors. An abstract of Dr. Ryba's report:

Mammalian Taste Receptors

The senses of vision, hearing, touch, olfaction, and taste have the critical roles of providing the organism with a faithful representation of the external world. In its simplest form, taste perception is responsible for basic food appraisal and bestows the organism with valuable but limited discriminatory power. For example**,** sweet receptors allow recognition of high-caloric food sources, while signaling through bitter receptors may stimulate behavioral aversion to noxious substances. Mammals are believed to distinguish only five modalities--sweet, sour, salty, bitter and umami (the taste of

monosodium glutamate). Because of this simplicity, there is hope that by understanding how taste is encoded at the level of the tongue and how this information is transmitted to the brain, insight will be gained into strategies used by the brain to decode sensory input. However, regrettably even the most fundamental questions of taste reception remain to be answered.

Researchers have been interested in basic questions of taste signal detection and information coding, and have focused primarily on sweet and bitter transduction. What are the receptors for sweet and bitter pathways? How is tastant specificity and taste discrimination accomplished? What is the topographic organization of sweet and bitter responding cells in the various taste buds and papillae? And, how is the information transmitted and encoded in the afferent nerves (i.e. are there specifically tuned lines)? To answer these questions we have set out to isolate genes involved in taste signaling, ideally the taste receptors, that can be used to mark the cells, define the corresponding signaling pathways and receptor specificity, generate topographic maps, and trace the respective neuronal connectivity circuits.

Recently, two novel G-protein coupled receptors (GPCRs) were isolated. They are now referred to as T1R1 and T1R2 and are expressed in distinct subsets of taste receptor cells. While these may be receptors for sweet, bitter or umami tastants, it was felt that two receptors are too few to sample the chemically diverse universe of sweet and bitter substances. Included in this presentation was a report of NIDCR's recent isolation and characterization of a novel family of about 40 human and rodent taste receptors (T2Rs) that appear to mediate bitter taste reception.

VI. "The Smell of Success and a Taste of the Future: The Chemical Senses in Year 2000" .....Dr. Steven Roper

Dr. Battey introduced Dr. Stephen Roper, President, Association for Chemoreception Sciences. Dr. Roper is also Professor of Physiology and Biophysics at the University of Miami School of Medicine, where his research focuses on the cellular and molecular biology of chemosensory transduction in taste buds. A summary of his presentation:

<u>"The Smell of Success and Taste of the Future: The Chemical Senses in the Year 2000."</u>

The Association for Chemoreception Sciences (AChemS) is one of, if not the largest international society for the study of the chemical senses, olfaction and gustation. AChemS sponsors an annual conference each spring for scientists and students from a diversity of disciplines, and from different backgrounds, including academic, clinical, and industrial laboratories. Members gather to share results from ongoing studies and establish new collaborations. These interactions have contributed to an impressive growth over the past two decades in our understanding of how chemical signals are sensed in the periphery and processed in the brain. Of particular note are the advances at the molecular level, namely the cloning of odorant receptors in 1991 by Linda Buck and Richard Axel, and of umami and bitter taste receptors in 2000 by Linda Buck, Nirupa Chaudhari, Nicholas Ryba, Charles Zuker and their associates. The

identification of chemosensory receptors at the molecular level has paved the way forimportant new advances at multiple levels--from the initial events of transduction to sensory coding in the brain. For example, by using genetically-manipulated mice that express a specific odorant receptor coupled with green fluorescent protein (GFP), scientists are able to track where the axons from peripheral olfactory receptor neurons that express that particular odorant receptor terminate in the olfactory lobe. Also, researchers have shown that simple volatile chemical compounds stimulate multiple odorant receptors, and conversely, a single odorant receptor is activated by more than one odorant. It is believed that there may be as many as 1000 different odorant receptors in humans.

As a consequence of this increased attention to the molecular basis for olfaction and taste, publications in chemical senses have strikingly increased in the past decade. This is especially true for high-visibility, widely-read journals such as Nature, Science, Nature Neuroscience, Cell, Neuron and others. These publications are attracting new researchers into the field and generating further enthusiasm for research in taste and olfaction.

Medical, industrial and applied research has also benefited from the renewed interest in the chemical senses. Important areas where attention is being focused include "electronic noses" used to detect buried explosives in mine fields, odors released from ripening fruit and vegetables, and in medical diagnoses. Digitally-released scents are being used to measure human olfactory capabilities and perhaps provide early detection of certain diseases. Digital scents are also being transmitted via the internet, used in electronic games, and used to help consumers design personal fragrances.

The chemical senses of taste and smell represent a rapidly expanding field of research where the outcomes are having profound and practical impacts in medical, military, industrial, and consumer uses. The future is quite promising for scientists interested in chemosensory research.

VII. Update on Trans-NIH Neuroinformatics Activities: The Human Brain Project..... Dr. Rochelle Small

Dr. Rochelle Small, Smell and Olfaction Program Director, of DER's Scientific Programs Branch presented an update on Trans-NIH Neuroinformatics Activities: the Human Brain Project.

Dr. Small described the Human Brain Project as a Federal inter-agency program established in 1993 to enhance research progress in the neurosciences and sensory sciences by supporting cooperative research efforts among neuroscientists and information scientists. The goals of the Human Brain Project are to develop technologies for producing interoperable databases and data management tools for analyzing, visualizing, manipulating, and modeling biological data. This initiative is sponsored by five federal agencies which include the National Institutes of Health, the

National Science Foundation, the National Aeronautics and Space Administration, the Department of Energy, and the Office of Naval Research.

In August 1999, four new program announcements were announced by the Human Brain Project and application receipt deadlines were increased from once a year, to twice yearly. 1) The Human Brain Project (Neuroinformatics): Phase I & Phase II, PAR-99-138; 2) Neuroinformatics Institutional Mentored Research Scientist Development Award, PAR-99-136; 3) Curriculum Development Award in Neuroinformatics Research and Analysis, PAR-99-135; and 4) Short Courses in Neuroinformatics, PAR-99-137.

The NIDCD currently supports three research projects sponsored by the Human Brain Project: 1) Dr. James Brinkley (University of Washington) to develop a database of 3-dimensional (3D) maps of language areas of the brain, that includes MR, PET and electrophysiologic data; 2) Dr. Gordon Shepherd (Yale University School of Medicine) to develop a set of databases integrating data for receptor genes, neuronal properties, and neural circuits for analyzing the functional organization of the olfactory system; and 3) Dr. Mark Ellison (University of California San Diego) to generate a database of 3D atlases of neuronal cell-types using high voltage electron microscopy.

VIII. Discussion of Future Agenda Topics..... Staff and Council

Dr. Battey opened the floor to Council members to solicit their ideas and requests for future agenda topics. Several suggestions were elicited and will be considered as plans are made for future meetings. Suggestions included the following: 1) including a scientific presentation at each Council meeting; 2) a report on the NIDCD contract portfolio; 3) periodic updates about the Clinical Trials Program; 4) a discussion of the role of the public member, and how other Institutes are utilizing them; and 5) progress reports on the implementation of recommendations from NIDCD Work Groups.

CLOSED SESSION

IX. Council Consideration of Pending Applications

The Council gave special attention to applications from foreign institutions and to applications involving issues related to protection of human subjects, animal welfare, biohazards and/or minority and gender representation in study populations as identified by the initial review groups.

A. <u>Research Project Grant Awards</u>

1. <u>Consideration of Applications</u>: On the Council's agenda was a total of 111 research grant applications; 88 applications had primary assignment to NIDCD, in the amount of $18.8 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to pay

first-year direct costs through the 30th percentile.

B. Special Programs Actions

1. Small Business Innovation Research Awards (SBIR). The Council recommended support for four Phase I (R43) and one Phase II (R44) application.

2. Small Business Technology Transfer (STTR): The Council recommended support for one Phase I application and one Phase II application.

3. Small Grants (R03): The Council recommended support for thirteen applications.

4. Conference Grants (R13): The Council recommended support for three applications.

5. Academic Research Enhancement Awards (R15): The Council recommended support for one application.

6. Exploratory Developmental Grants (R21): The Council recommended support for one application.

7. Education Projects - RFA DC99-02 (R25): The Council recommended support for two applications.

8. Mouse Mutagenesis - RFA MH99-007 (U01): - The Council recommended co-funding support of two applications.

D. Career Development Programs

1. Independent Scientist Award (K02): The Council recommended support for one application.

2. Academic /Teacher Award (K07): The Council recommended support for one application.

3. Mentored Clinical Scientist Development Award (K08): The Council recommended support for two applications.

4. Mentored Patient-Oriented Research Award (K23): The Council recommended support for one application.

X. Adjournment: The meeting was adjourned at 2:30 p.m. on May 24, 2000.

XI. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.[1]

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Craig A. Jordan, Ph.D.
Executive Secretary
National Deafness and Other Communication
Disorders Advisory Council

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James F. Battey, Jr., M.D., Ph.D.
Chairman
National Deafness and Other Communication
Disorders Advisory Council

Director
National Institute on Deafness and
Other Communication Disorders[2]

Jeannie Combs
Council Assistant

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[1]These minutes will be formally considered by the Council at its next meeting; corrections or notations will be incorporated in the minutes of that meeting.

APPENDICES

PAGE

Appendix 1

Roster

National Deafness and Other Communication Disorders Advisory Council

Chairperson

Battey, James F., Jr., M.D., Ph.D.
Director
National Institute on Deafness and Other Communication Disorders
Bethesda, Maryland 20892

BERNDT, Rita S., Ph.D. 2002
Professor
Department of Neurology
University of Maryland
School of Medicine
Baltimore, Maryland

BURD, Gail D., Ph.D. 2003
Professor and
Associate Department Head
Molecular and Cellular Biology
University of Arizona
Tucson, Arizona

COHEN, Bernard, M.D. 2002
Morris B. Bender
Professor of Neurology
Department of Neurology
Mount Sinai School of Medicine
City University of New York
New York, New York

COREY, David P., Ph.D. 2001
Professor of Neurobiology
Harvard Medical School
Neurobiologist, Department of Neurobiology
Massachusetts General Hospital
Boston, Massachusetts

DRESSER, Rebecca S., J.D. 2001
Professor, School of Law
and Program for the Humanities in Medicine
Washington University School of Law
St. Louis, Missouri

DUBNO, Judy R., Ph.D. 2003
Professor
Department of Otolaryngology-
Head and Neck Surgery
Medical University of South Carolina
Charleston, SC

EMANUEL, Beverly S., Ph.D. 2004
The Charles E.H.Upham Professor of Pediatrics
University of Pennsylvania School of Medicine;
Chief, Division of Human Genetics and
Molecular Biology
The Children's Hospital of Philadelphia
Philadelphia, PA

HARRIS, Bernard A., Jr., M.D. 2002
Vice President
Microgravity and Life Science
SPACEHAB, Inc.
Houston, Texas

HOY, Ronald R., Ph.D. 2003
Professor
Section of Neurobiology and Behavior
Cornell University
Ithaca, New York

JONES, Jacqueline E., M.D. 2002
Associate Professor of
Clinical Otolaryngology
Cornell University Medical College
New York, New York

LINARES-ORAMA, Nicolas, Ph.D. 2004
University of Puerto Rico
Medical Sciences Campus
San Juan, Puerto Rico

MADISON, John P., Ed.D. 2004
Associate Professor
Department of English
National Technical Institute for the Deaf
Rochester, NY

MEISLER, Miriam H., Ph.D. 2003
Professor
Human Genetics Department
School of Medicine
University of Michigan
Ann Arbor, Michigan

SORKIN, Donna L. 2002
Alexander Graham Bell Association
for the Deaf and Hard of Hearing
Washington, DC

STERN, Virginia W. 2001
American Association for the
Advancement of Science
Washington, D.C.

TAYLOR, Orlando L., Ph.D. 2001
Dean
Graduate School of Arts & Sciences
Howard University
Washington, D.C.

TITZE, Ingo R., Ph.D. 2004
Department of Speech Pathology
and Audiology
University of Iowa
Iowa City, IA

WOLF, Gregory T., M.D. 2001
Chair, Department of Otolaryngology-
Head and Neck Surgery
University of Michigan Medical Center
Ann Arbor, Michigan

Ex-Officio Members:

BECK, Lucille B., Ph.D.
Director
Audiology and Speech Pathology
Service
Department of Veterans Affairs
Washington, D.C.

FRANKS, John R., Ph.D.
Chief, Bioacoustics and Occupational
Vibration Section
Physical Agent Effects Branch
Division of Biomedical and Behavioral Science
National Institute for Occupational
Safety and Health
Cincinnati, Ohio

HOFFER, Michael E., M.D.
Department of Otolaryngology
Naval Medical Center
San Diego, California

SHALALA, Donna E., Ph.D.
Secretary
Department of Health and
Human Services
Washington, D.C.

KIRSCHSTEIN, Ruth L., M.D.
Acting Director
National Institutes of Health
Bethesda, Maryland

EXECUTIVE SECRETARY

JORDAN, Craig A., Ph.D.
Acting Director
Division of Extramural Activities, NIDCD
Bethesda, Maryland

Appendix 2

ATTENDANCE LIST

Other than Council members, attendees at the May 2000 Council meeting included:

NIDCD Staff:

Office of the Director
Luecke, Donald H., M.D., Deputy Director
Phillips, Isabelle, Secretary
Lopez, Joyce, Program Specialist

Office of Administration
Kerr, W. David, Executive Officer

Financial Management Branch
Sparks, Patience, Budget Officer

Information Systems Management Branch
Hamilton, Sue, Chief

Science Policy and Legislation Branch
Smith, Mary Acting Chief
Wong, Baldwin Program Analyst

Division of Extramural Research
Dobie, Robert A., M.D., Director
Combs, Jeannie, Program Analyst
DaSilva, Maria, Program Assistant
Holmes, Debbie, Secretary

Grants Management Branch
Hunt, Sharon, Chief
Chicchirichi, David, Grants Management Specialist
Dabney, Sherry, Grants Management Officer
McNamara, Castilla, Grants Management Specialist
Ranney, Meigs, Grants Management Officer

Scientific Programs Branch
Cooper, Judith, Ph.D., Chief; and Program Director, Language
Davis, Barry, Ph.D., Program Director, Taste/Gustation
Small, Rochelle, Ph.D., Program Director, Smell/Olfaction
Gulya, Julie, M.D., Program Director, Clinical Trials

Hearing and Balance/Vestibular Section
Donahue, Amy, Chief; and Program Director, Hearing
Freeman, Nancy, Ph.D., Program Director, Hearing
Johnson, Thomas, Ph.D., Program Director, Hearing
Luethke, Lynn, Ph.D., Program Director, Hearing
Sklare, Daniel A., Ph.D., Program Director, Balance/Vestibular

Scientific Review Branch
Jordan, Craig A., Ph.D., Chief
Oaks, Stanley C., Ph.D., Scientific Review Administrator
Stick, Melissa J., Ph.D., M.P.H., Scientific Review Administrator
Kemmerle, Donna, Grants Technical Assistant

Center for Scientific Review, NIH
Kimm, Joseph, Ph.D., Scientific Review Administrator
Kenshalo, Daniel, Ph.D., Scientific Review Administrator
Meadow-Orlans, Kathryn, Ph.D., Scientific Review Administrator
Sostek-Miller, Anita, Ph.D., Scientific Review Administrator

Others
Moss, Sharon, Ph.D., American Speech and Hearing Association
Roper, Stephen, Ph.D., President, Association for Chemoreception Sciences
Dr. Nicholas Ryba, National Institute of Dental and Craniofacial Research

Appendix 2

NIDCD Director's Report Slides

As Presented By
James F. Battey, Jr., M.D., Ph.D.
NDCD Advisory Council Meeting

May 24, 2000